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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,701	01/30/2001	Jonathan Allan Coates	IAFG 14 C2	9492

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EXAMINER

KRASS, FREDERICK F

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/771,701

Applicant(s)

COATES ET AL.

Examiner

Frederick Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-58 is/are pending in the application.
- 4a) Of the above claim(s) 25-30, 34-39 and 43-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-24, 31-33, 40-42 and 49-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 07/835,964.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Restriction and Election of Species Requirements

The restriction requirement is withdrawn in view of Applicant's explanation.

The election of species requirement is maintained. Applicant's election of the ultimate species "AZT" in Paper no. 6 is acknowledged. Insofar as that election may be with traverse, Applicant is reminded that the purpose of an election of species requirement, as opposed to a restriction between groups of claims, is only to narrow the search required by the examiner during prosecution; upon allowance of a generic claim, all nonelected species falling within that claim will also be allowed.

Claims 25-30, 34-39 and 43-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species.

Duplicate Claim Warning

Applicant is advised that should claim 20 be found allowable, claim 22 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

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If B-L-2'-deoxy-3-thiacytidine and (-)-(2R, cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5yl)-(1H)-pyrimidin-2-one are the same compound, then claims 20 and 22 are identical. Additionally, various dependent claims are identical as well, for example claims 23, 32 and 41 are substantial duplicates. Applicant is advised to carefully review and amend the claims to avoid any such overlaps.

Indefiniteness Rejection

Claims 32, 33, 40, 41, 42 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32 and 41 are rejected insofar as the term "said 2',3'-dideoxy nucleoside" finds no antecedent basis. Claims 33, 40, 42 and 49 are rejected insofar as they do not ameliorate this omission.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 19-24, 31-33, 40-42 and 49-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rideout et al (USP 4,724,232) in view of Liotta et al (USP 5,539,116).

The primary reference discloses applicant's elected species of 2',3'-dideoxy nucleoside/anti-HIV D-nucleoside compound, namely AZT, and its use to treat AIDS. It differs from the instant claims insofar as it does not specifically disclose the instantly claimed oxathiolan compound/L-nucleoside ("BCH-189"). It does, however, clearly suggest that additional antiviral nucleosides can be administered therewith (column 4, lines 7-19). Dosages range from 5 to 250mg/kg and from 5 to 500 mg/unit dose (column 3, lines 35-53).

The secondary reference discloses the use the purified, isolated (-) enantiomer of BCH-189 to treat AIDS. It differs from the instant claims insofar as, although it teaches that (-) BCH-189 and AZT are therapeutically equivalent (column 2, lines 60-64), it does not specifically disclose a mixture of the two.

It is obvious to combine equivalents known for the same purpose. More specifically, it is obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. See MPEP 2144.06. Consonant therewith, it would have been obvious to have combined (-) BCH-189 and AZT, both of which are known anti-AIDS agents as disclosed by the primary and secondary references, in order to form a third composition to be used for that very same purpose. Regarding the specific dosages set forth by instant claims 50-58, these appear to be within the ranges set forth

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by the prior art for anti-AIDS nucleosides; in any case, it is well within the skill of an individual of ordinary skill in the art to determine optimum/workable values for the result-effective variable of therapeutic dose, and it would have been obvious to have done so here in order to optimize therapeutic effectiveness for individual patients, who differ widely in weight, severity of pathology, etc. See MPEP 2144.05, Section II, subsections A and B.

Obviousness-Type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 20-24, 31-33, 40-42 and 49-58 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-26, 41-45 and 53-60 of U.S. Patent No. 6,180,639 in view of Liotta et al (USP 5,539,116).

The instant claims are clearly coextensive in scope with the conflicting claims, differing only insofar as the instant claims do not specifically recited the specific amount

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of no more than 5% w/w (+) enantiomer of BCH-189 found in the conflicting claims. It would have been obvious to have used an amount greater than 5 weight percent (+) enantiomer, however, since it is well-known in the art that the instantly claimed L-nucleoside is effective as the pure isomer, in "enantiomerically enriched" form, or even when present in the racemate, as taught (and claimed) by USP 5,539,116.

2) Claim 19 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12, 27-40 and 46-52 of U.S. Patent No. 6,180,639.

The instant claims are clearly coextensive in scope with the conflicting claims, differing only insofar as the instant claims do not specifically recite the additional antiviral agents of instant claim 19 (AZT, etc). The conflicting claims instead recite either other "antiviral agents" generally, or "2,3-dideoxynucleosides" as a class. It would have been obvious to have used specific known antiviral agents such as AZT as specific examples within those broad classes, however, since the species recited instantly are all well-known and commercially available anti-AIDS agents.

Status of Claims

All pending, elected claims have been rejected over prior art and are not allowable as presently advised.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (703) 308-4335. The examiner can normally be reached on Monday, Tuesday and Thursday from 9am to 5pm and on Friday from 11am to 7pm. The examiner is off Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached at (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0193.

Frederick Krass
Primary Examiner
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